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| EXAMINER | |
|---|---|
| DIRAMIO, JACQUELINE A | |
| **ART UNIT** | **PAPER NUMBER** |
| 1641 | |

| NOTIFICATION DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/762,784 | CHILDERS ET AL. | |
| | Examiner | Art Unit | |
| | JACQUELINE DIRAMIO | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,7-14,16-18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) *11-14,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-10,18,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Claims*

1. Applicant's amendments to claims 1, 7, 11 – 13, and 16 – 18 are acknowledged, as well as the cancellation of claim 6 and the addition of new claim 21.

2. Currently, claims 1, 7 – 10, 18, 20 and 21 are pending and under examination. Claims 11 - 14, 16 and 17 are acknowledged as withdrawn as drawn to a non-elected invention.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 1, 7, 18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (US 2005/0019953) in view of Burke et al. (US 2008/0098802) and Ward (US 5,410,504).

Groll teaches a self-calibrating disposable blood test strip (device) comprising:

a substrate configured for carrying a chemical reagent; and

circuitry formed on the substrate, the circuitry comprising:

a measurement (sensor) portion, i.e. measurement contact pads, associated with the chemical reagent to enable measurement of at least one of a presence and a concentration of a blood analyte;

an information storage portion, i.e. information contact pads, configured to store information indicative of at least one calibration value of the chemical reagent for calibrating operation of a meter to accurately measure and monitor a test of the blood analyte; and

an input and output arrangement formed on the substrate and in electrical communication with the information storage portion to enable the meter to access the at least one calibration value from the information storage portion;

wherein the information storage portion is electrically connected to a portion of the measurement portion of the circuitry and includes at least one electrically conductive element including a plurality of electrically conductive contact pads (elements) each contact pad being configured to be physically altered by severing the conductive path (i.e. shorting via a fusible link) and a number, N, of the contact pads in a determinable order producing a characteristic measurement, such as resistance or conductivity, that is indicative of the at least one calibration value of the chemical reagent, the N contact pads producing $2^N$ different possible calibration values (see Figures 1-4 and 10-15; and paragraphs [0010], [0011], [0014], [0035], [0036], [0038], [0039], [0041], [0042], [0047], [0061], [0064]-[0070], [0075]-[0084], and [0094]).

Although Groll teaches that the characteristic measurement of the contact pads can comprise resistance or conductivity (see paragraph [0042]), Groll fails to teach that the

characteristic measurement can also be impedance. Secondly, Groll teaches that the potential conductive links can be sensed or induced via "capacitive means" (see paragraph [0042]), however, Groll fails to specifically teach that the electrically conductive elements of the information storage portion are either a plurality of inductors arranged in series or a plurality of capacitors arranged generally in parallel.

Burke et al. teach a system and method for accurately measuring an analyte in a fluid sample, wherein the system comprises a test strip with associated electrodes. The application of a fluid sample, i.e. blood, to the test strip results in sample covering the test electrodes, which results in the increase of the current response of the test electrodes because the sample is reacting with a reagent present on the test electrodes. The response current will reach a stable state, which indicates the impedance of the sample. The stable state response could also be measured as current or voltage and the impedance can be calculated therefrom. In addition, one skilled in the art would recognize that measurements of impedance, resistance, current, conductivity or charge are interchangeable, wherein it is only necessary to adjust the measurement and correction mathematics to account for which measure is being employed (see Abstract; and paragraphs [0059] and [0061]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Groll the characteristic measurement of the electrically conductive elements (i.e. contact pads) comprising impedance as taught by Burke et al. because Burke et al. teach that a system comprising a test strip with associated electrodes, i.e. electrically conductive elements, can accurately measure an analyte in a fluid sample by monitoring the impedance of the test electrodes as the electrodes react with a fluid sample of

interest. In addition, it would have been obvious matter of design choice to measure various electrical properties of the contact pads of Groll as taught by Burke et al. because Burke et al. teach that one skilled in the art would recognize that measurements of impedance, resistance, current, conductivity, or charge are interchangeable, wherein it is only necessary to adjust the measurement and correction mathematics in order to account for which measure is being employed.

Ward teaches a method of constructing a memory on a semiconductor substrate from a plurality of capacitor elements organized in a plurality of rows and columns, i.e. in parallel. The capacitor array may be used for storing information, such as a ROM. Each capacitor is used to store one bit of information, wherein a capacitor storing a "1" will have a different capacitance than a capacitor storing a "0" (see Abstract; column 1, lines 63-68; column 2, lines 1-68; and column 3, lines 1-30).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Groll an array of capacitors arranged in parallel as the electrically conductive elements as taught by Ward because Ward teaches the benefit of creating a parallel capacitor array on a semiconductor substrate in order to create a memory that can be used for storing information, such as a ROM, wherein each capacitor is used to store one bit of information. In addition, the array of parallel capacitors taught by Ward is merely creating the same encoded information by storing bits of information as either a "1" or "0" within each capacitor, which is the same encoded information created via the contact pads of Groll (see paragraphs [0077]-[0079] of Groll).

With respect to Applicant's claim 7, Groll teaches that the test device can comprise a set of test devices with the information storage portion of each test device storing substantially the same information (see paragraphs [0012], [0066] and [0070]).

With respect to Applicant's claim 18, the limitations of this claim are discussed above with respect to claim 1.

With respect to Applicant's claim 20, Groll teaches that the information storage portion is inseparable from the disposable test strip (see paragraph [0065]).

With respect to Applicant's claim 21, the limitations of this claim are discussed above with respect to claim 1.

4. Claims 8 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (US 2005/0019953) in view of Burke et al. (US 2008/0098802) and Ward (US 5,410,504), as applied to claim 1 above, and further in view of Mandecki (US 2002/0006673).

The Groll, Burke et al. and Ward references, which were discussed in the 103(a) rejection above, fail to teach that the circuitry of the substrate of the device comprises a semiconductor portion and a non-volatile memory, wherein an electrical signal generator external to the device is configured to send an electrical signal to the non-volatile memory to cause storage of the information in the information storage portion.

Mandecki teaches transponders for use in methods of detecting biomolecules in a sample, wherein the transponders comprise a solid phase, a reagent or biomolecule binding element, and an index number or memory element that is electronically encoded on the transponder. The index number can be unique to each solid phase, and is retrievable by a scanner device at any

time during an assay. The index number can relate to the time and date on which the assay was performed, the patient's name, a code identifying the type of assay, catalog numbers of reagents used in the assay, or data describing the progress of the assay. The memory element can be encoded by a user just before, during or after a biological material is deposited on the surface of the transponder. The memory element is encoded with data sent by electromagnetic waves from a remote scanner read/write device, wherein the scanner read/write device further receives the encoded data transmitted by the transponder (see Abstract; and paragraphs [0007], [0009], [0021], [0027], [0031] and [0032]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Groll, Burke et al. and Ward a memory element, wherein an external signal generator, i.e. scanner read/write device, is configured to send an electrical signal to the memory element to cause storage of information, as taught by Mandecki because Mandecki teaches the benefit of including a memory element on a transponder or solid phase device for detecting biomolecules in a sample, wherein the memory element can be encoded by an external scanner read/write device, in order to allow for encoding of the memory element by a user just before, during or after a biological material is deposited on the surface of the transponder. This encoding of the memory element allows for information to be stored within the transponder device for later retrieval, wherein the information can relate to the time and date on which the assay was performed, the patient's name, a code identifying the type of assay, catalog numbers of reagents used in the assay, or data describing the progress of the assay.

***Response to Arguments***

5. Applicant's arguments filed April 29, 2009 have been fully considered but they are not persuasive. Applicant argues, pages 9-11, that the combination of Groll (US 2005/0019953) in view of Burke et al. (US 2008/0098802) and Ward (US 5,410,504) fails to teach the amendments to the independent claims, including: impedance elements on a substrate, wherein the impedance elements can be physically alterable; or that a $2^N$ number of calibration values can be produced by the impedance elements. However, these arguments are not found persuasive.

To begin, Applicant appears to be arguing against the references individually, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Secondly, it is agreed that Groll fails to teach a plurality of "impedance" elements, but merely teaches a plurality of electrically conductive elements in the form of contact pads, which provide a measurement value in the form of either resistance or conductivity (see paragraphs [0039] and [0042]). However, the secondary reference of Burke et al. was combined with Groll in order to provide evidence that the measurement values of electrodes or contact pads, such as impedance, resistance, current, conductivity, or charge, are interchangeable, wherein it is only necessary to adjust the measurement and correction mathematics in order to account for which measure is being employed. Therefore, it would have been obvious to one of ordinary skill in the art to determine which value to measure, such as impedance, resistance, or conductivity, from the contact pads of Groll as taught by Burke et al. given that these measurement values are

interchangeable, wherein it is only necessary to adjust the measurement and correction mathematics in order to account for which measure is being employed, and thus, the determination of which value to measure would be an obvious matter of design choice.

With respect to Applicant's argument over the elements of Groll not being "physically alterable," this argument is not found persuasive because Groll specifically teaches that their contact pads can be physically altered by severing the conductive paths between pairs of the contact pads, i.e. shorting via fusible link (see paragraphs [0078] and [0079]). Thus, Groll does in fact teach that their contact pads are configured to be physically alterable, such as by shorting via fusible link.

Finally, with respect to Applicant's argument that neither Burke nor Groll teach that a $2^N$ number of calibration values can be produced by the impedance elements, this argument is not found persuasive because Groll does in fact teach that their contact pads are capable of producing a $2^N$ number of calibration values (see paragraph [0078] in particular). Therefore, because Groll teaches that their contact pads are capable of producing a $2^N$ number of calibration values, and Burke teaches the interchangeability of measuring impedance versus resistance or conductivity, as discussed above, the combination of Groll in view of Burke meets this limitation of the claim.

In conclusion, the previous 103(a) rejection over claims 1, 7, 18, and 20 as being unpatentable over Groll (US 2005/0019953) in view of Burke et al. (US 2008/0098802) and Ward (US 5,410,504) is maintained.

***Conclusion***

6. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/
Examiner, Art Unit 1641

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
July 29, 2009